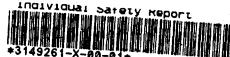


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	CTS REPORTING PROGRAM	FOR	ONSUMER F #3149; IT WASHINGTON, PA 19		or som son hash son son het All
A. Patient information			Page of	L	
1. Patient identifier 2. Age at tin			C. Suspect med	ication(s)	
of event:	17	4. Weight	1. Name (give labeled stre	ngth & mfr/labeler, if kr	own)
01170943 Or	) fem	1	#1 Extra Strength TY	LENOL product	
In confidence of birth:	(X)mal	or	#2		
B. Adverse event or pr	Oduct problem	e 78 kgs	2. Dose, frequency & route	e used 3. Therapy d	
. A Moveme event and/or	Product amblem to a det	ecte los elformasis		from to Jose	ates (if unknown, give du est estimate)
<ol><li>Outcomes attributed to adverse e (check all that apply)</li></ol>	vent	cots/mairunctions)	#1 30 g over 8 hours		/94; 1 day
	( ) disability		#2 4. Diagnosis for use (indica	42	
(X) douth 9/20/94 [mo/day/yr]	( ) congenital anoma	nky	#1 toothache	tion)	5. Event abated after u
( ) life-threatening (X) hospitalization - initial or one	( ) required intervent	ion to prevent			stopped or dose redu
(X) hospitalization - initial or pro	longed {	ment/damage	12		#1 ( ) Yes ( ) No
Date of event	( ) other:		6. Let # (if known)		
0/25/0/	Date of this report		#1 Unknown	7. Exp. date (if known)	#2 ( ) Yes ( ) No
(motasytyr)	Ima/dev/yr] 10/16/98	3	#2	Unknown	8. Event reappeared after
Describe event or problem				#2	reintroduction
Otification via liei	-4	I	9. NDC # - for product proble	ems only (if known)	#1 ( ) Yes ( ) No
otification via litigation	of case summaries prov				
hysician/co-author of liter 37:1112-7). Info provided b	ature report (N Engl J	Med 1997;	10 Connecies		#2 ( ) Yes ( ) No (
37:1112-7). Info provided b	ased on extracted data	from med-	<ol> <li>Concomitant medical pro- penicillin VK (9/2</li> </ol>	ducts and therapy dates	lexclude treatment of av
cal records of pts hospital etween 1/1/92 & 4/30/95. Ac	ized for acetaminophen	ingestion	Sect 87 cont: TP=4	9 Alban a	
M with hx of regular etha	cording to extracted da	ata, a 37	Tbili=9.3, GGT=138	., ALD-2.0, ALT=3	10, AST=3290,
LENOL® (ACCIDENTAL OVERDOS	Not use ingested Extra	Strength	urine culture-e.co	L vence	iluc=41, Creat=5.1,
T toothache. Pt had NAUSEA	1 Wer B hr period on		G. All manufacture	rc.	
ays PTA. On 9/27/94 pt was a	d voniling & abdominal	pain 2	. Contact office - name/addre	es & mfring site for de	vices 2 D
cute liver failure (HEPATIC	FAILURE & Paris	noses of	McNeil Consumer Pro	ducts Company	
INICOURTY AF EXDILEG	(DEATH) on 0/20/0/		Medical Affairs	and a support	215-233-7820
TOTIOTION HEU PECOPES 1	Odicate of increase to	_	7050 Camp Hill Road		3. Report source
arruor according to	brother by L.J.		Ft. Washington, PA	19034	Icheck all that
cc accoming emersis, & abdom	inal pain on been	. 1			( ) foreign
SOURCE TO COMPONENTION DISUBL	DED & CCACTROTUTES	T T			( ) study
AAN I C LECELAGO MOCOMIZIO	& Undervent home die	. 1			( ) literature
T TOTAL PL HOU LOCAL SEIZIN	TAS (COMBAIL STOURS & .	L			( ) consume
dence of intracranial edema	Pt expired after eve	thorical 4.	Date received by menufacture (moldeylyr)	er 6.	health
	The street extended		10/13/98	(A) NDA # 17-552	(X) professio
		6. 1	r sviD, protocol #	IND #	( ) userfacil
event teste/leboratory data, includi	ng dates			PLA #	company ( ) representa
5/94 WBC=25.7, AST=13290, A	lkP=96, Tbili=4.4. TP=6	5,9.		pre-1938 ( ) Y	
217, Creat-3.3, K=6.8, Cl=	90 CO2=15 Alb=2 A	)=12200- /. T	ype of report check all that apply)	отс	( ) other:
* * * accrommobileti=/* FION	PVP Doggetter			product (X) Y	1
c=positive, a-HCV=positive	. HBsAg=negative (See S		) 5-day (X) 15-day	8. Adverse event term	
		1	) 10-day ( ) periodic	J.	10)
		<b>!</b> `	) Initial (X) follow-up # q	OVERDOSE ACCID	NAUSEA VONIT
		9. M	fr. report number	LIVER FAILURE	KIDNEY FAILURE
er relevant history, including preexis pregnancy, smoking and alcohol u	ting medical conditions		03966A	COAGULATION DIS	HEHORRHAGE GI
pregnancy, smoking and alcohol u	se, hepatic/renal dysfunction.	allergies, oyl		CONVULSION	DEATH
	rny & aliza		nitial reporter		
Scar arink on a	2/25/0/ s km / km .				
T - 30 OF CHOS. DX OT CM	Nina 1 1 . sa		MO		
a.a. ucilila (Sect RV cou	111 3-40C 1-4	D		Medical Ctr	
lenative no ex -	o magazite,	a-HAV I			
Degative, PT=50.2, PTT=59.1, 11.6, HCT=32.7, PLT=36, PT=3	CY=707 - 0 -20 -2-		Boulevar		3



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

4. Initial reporter also sent report to FDA

physician

(X) Yes ( ) No

( ) Yes ( ) No (X) Unk